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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,874	06/23/2000	Markus Pompejus	BGI-123CP	2764

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/04/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/602,874

Applicant(s)

POMPEJUS ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (Paper No. 14, mailed on February 11, 2003), Applicants filed a response and amendment received on August 11, 2003 (Paper No. 16). Said amendment amended Claims 29 and 34. Claims 25-34 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/141,031 filed on June 25, 1999, 60/142,690 filed on July 1, 1999, and 60/151,251 filed on August 27, 1999.

Also as previously noted, the instant application is not granted the benefit of priority for the 12 foreign applications filed in Germany because certified copies have not yet been filed.

Information Disclosure Statement

3. Applicants cite that an information disclosure statement is forthcoming; none has been received.

Withdrawn - Objections to the Specification

4. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicants' amendment.

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5. Previous objection to the Abstract for containing the abbreviation “MR” without definition is withdrawn by virtue of Applicants’ amendment.
6. Previous objection to the specification for being confusing is withdrawn by virtue of Applicants’ amendment and/or in light of their arguments.
7. While the Examiner withdraws the objection to the specification about being confusing in the Tables as to the assignment of functionality based on a reconsideration, the Examiner requests that in response to the instant Office action, Applicants describe the means for assessing functionality in their remarks, for the record if not for the specification. Such an explanation would be very useful to clarify the record and the specification.

Withdrawn - Claim Objections

8. Previous objection to Claim 29 for a typographical error is withdrawn by virtue of Applicants’ amendment.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

9. Previous rejection of Claim 34 under 35 U.S.C. § 112, second paragraph, is withdrawn by virtue of Applicant's amendment removing reference to the complement of the sequence.
10. Previous rejection of Claim 34 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "about" is withdrawn by virtue of Applicants' amendment.

New or Maintained - Claim Rejections - 35 U.S.C. § 112

11. Previous rejection of Claim 29 under 35 U.S.C. § 112, second paragraph, as being indefinite for the species *Corynebacterium acetophilum* and for reference to generic *Brevibacterium* species and *Corynebacterium* species in Table 3 is maintained; all other points are withdrawn by virtue of Applicant's amendment. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that an Abstract of Murooka *et al.* clarifies this species; the Examiner disagrees. Firstly, no Abstract was received; the Examiner obtained a copy on-line. Secondly, the Abstract merely states "An enzyme that can synthesize O-alkylhomoserine from alcohols and O-acetylhomoserine was purified from *Corynebacterium acetophilum*", and this does not aid one of skill in the art to understand the metes and bounds of terms (i.e., identify the species). Perhaps the entire reference would be useful.

With respect to the reference to generic *Brevibacterium* species and *Corynebacterium* species in Table 3, Applicants argue that one of skill in the art would know what these terms means; the Examiner disagrees. The Table refers to species of the genera *Brevibacterium* and *Corynebacterium*. While the Examiner agrees that one of skill in the art knows what the genus

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names encompass, the nature of the species referred to in the Table and specifically limited to in the claim is unclear.

Clarification of both issues is required.

12. Previous rejection of Claim 31 under 35 U.S.C. § 112, second paragraph, as being indefinite for the Markush member “enzymes” as a fine chemical is maintained. Applicants’ arguments have been fully considered but are not persuasive for the following reasons.

Applicants cite Hawley’s Condensed Chemical Dictionary but no copy has been provided of the citation and Applicants do not quote the source verbatim. Thus, the Examiner cannot assess the validity of Applicants’ arguments in light of this reference. Moreover, the Examiner can find no definition of “fine chemical” that includes the complex, three-dimensional, functional entities of enzymes. Thus, the Examiner maintains that identifying an enzyme as a fine chemical is repugnant to the art. The Examiner suggests writing an independent claim drawn to the production of enzymes.

13. (New) Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “glucose resistance amylase regulator activity” is wholly unclear. What does this protein do? Regulate amylase? How? Is there some glucose resistance? What is the mechanism? The metes and bounds of this function are wholly unclear as based on the very limited information presented in the specification and/or the art.

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14. Previous rejection of Claims 25-34 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that "SEQ ID NO:1 contains sufficient sequence information to encode the specified activity, e.g., glucose resistance amylase regulator activity." The Examiner emphatically disagrees for the reasons previously set forth, which remain unaddressed by applicants, as follows:

- a) SEQ ID NO:1 encodes a 138 amino acid protein that does not appear to be a full-length glucose resistance amylase regulator based on the art.
- b) SEQ ID NO:1 has little sequence homology with other glucose resistance amylase regulators in the art.

The functional assignment of SEQ ID NO:2 as a glucose resistance amylase regulator based solely on sequence homology is not convincing. Moreover, no functional assays have been performed to identify SEQ ID NO:2 as a glucose resistance amylase regulator. For all these reasons, the assignment of SEQ ID NO:1 encoding a full-length (or functional portion thereof) protein that encodes a glucose resistance amylase regulator is not convincing. Due to the comprising language relating to the nucleotide sequence, use of a full-length sequence (an open reading frame) related to SEQ ID NO:1 is within the scope of the claim. Yet, no full-length encoding sequence has been described. Thus, the rejection of Claims 25-33 is maintained.

With respect to the rejection of Claim 34, the rejection is maintained. Applicants argue that the functional limitation in conjunction with the structural limitations limits the scope so that it is supported by the specification as originally filed. The Examiner would agree with this assessment is the function of "glucose resistance amylase regulator activity" was clear. If a clear activity were defined, rejection of Claim 34 would be maintained for the reasons cited above for Claims 25-34.

Maintained - Claim Rejections - 35 U.S.C. § 101

Previous rejection of Claims 25-34 under 35 U.S.C. § 101 is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that one of skill in the art, with the information provided by the specification, would conclude that "the asserted utility is more likely than not true"; the Examiner disagrees. For the reasons cited above relating to the written description rejection, one of skill in the art would not conclude that SEQ ID NO:1 encodes a glucose resistance amylase regulator activity, whatever that may be. Moreover, the Examiner notes that the production of a "fine chemical" is not a specific utility. Without more direction about why overexpression of SEQ ID NO:1 helps the production of a specific fine chemical, a specific utility for the instant claims cannot be supported.

15. Previous rejection of Claims 25-34 under 35 U.S.C. § 112, first paragraph, enablement, is maintained for the reasons cited above under utility.

Examiner's Comments

16. The Examiner notes that while other disclosures of the *Corynebacterium glutamicum* genome teach SEQ ID NO:1, all fail to identify SEQ ID NO:1 as encoding a glucose resistance amylase regulator activity protein or even as an open reading frame. Applicants' attention is drawn to GenBank Accession Number AP005281 by Nakagawa *et al.*, which is reflective of EP 1108790. The Examiner performed a BLAST search of AP005281 (290675-291188), which portion aligns exactly with SEQ ID NO:1, and no convincing homologies to any identified proteins were found (see attachment).

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Conclusion

17. Claims 25-34 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



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KMK

October 21, 2003